

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

**I. (a) PLAINTIFFS**

Margaret Thornton

(b) County of Residence of First Listed Plaintiff Pineles, FL  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Barrett Beasley  
Salim-Beasley, LLC  
1901 Texas Street  
Natchitoches, LA 71457  
(318) 238-1827

**DEFENDANTS**

GLAXOSMITHKLINE LLC

County of Residence of First Listed Defendant Philadelphia, Pennsylvania

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

Pepper Hamilton, LLP  
3000 Two Logan Square  
18th & Arch Streets  
Philadelphia, PA 19103  
Telephone: (215) 981-4000

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                                   | DEF                        |   | PTF                        | DEF                                   |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1            | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 |
| Citizen of Another State                | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5            |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3            | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6            |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

- |   |  |   |  |   |  |
|---|--|---|--|---|--|
| <input type="checkbox"/> 110 Insurance<br><input type="checkbox"/> 120 Marine<br><input type="checkbox"/> 130 Miller Act<br><input type="checkbox"/> 140 Negotiable Instrument<br><input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment<br><input type="checkbox"/> 151 Medicare Act<br><input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans)<br><input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits<br><input type="checkbox"/> 160 Stockholders' Suits<br><input type="checkbox"/> 190 Other Contract<br><input type="checkbox"/> 195 Contract Product Liability<br><input type="checkbox"/> 196 Franchise | <b>PERSONAL INJURY</b><br><input type="checkbox"/> 310 Airplane<br><input type="checkbox"/> 315 Airplane Product Liability<br><input type="checkbox"/> 320 Assault, Libel & Slander<br><input type="checkbox"/> 330 Federal Employers' Liability<br><input type="checkbox"/> 340 Marine<br><input type="checkbox"/> 345 Marine Product Liability<br><input type="checkbox"/> 350 Motor Vehicle<br><input type="checkbox"/> 355 Motor Vehicle Product Liability<br><input type="checkbox"/> 360 Other Personal Injury<br><input type="checkbox"/> 362 Personal Injury - Medical Malpractice | <b>PERSONAL INJURY</b><br><input type="checkbox"/> 365 Personal Injury - Product Liability<br><input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability<br><input type="checkbox"/> 368 Asbestos Personal Injury Product Liability<br><b>PERSONAL PROPERTY</b><br><input type="checkbox"/> 370 Other Fraud<br><input type="checkbox"/> 371 Truth in Lending<br><input type="checkbox"/> 380 Other Personal Property Damage<br><input type="checkbox"/> 385 Property Damage Product Liability | <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881<br><input type="checkbox"/> 690 Other<br><input type="checkbox"/> 710 Fair Labor Standards Act<br><input type="checkbox"/> 720 Labor/Management Relations<br><input type="checkbox"/> 740 Railway Labor Act<br><input type="checkbox"/> 751 Family and Medical Leave Act<br><input type="checkbox"/> 790 Other Labor Litigation<br><input type="checkbox"/> 791 Employee Retirement Income Security Act | <input type="checkbox"/> 422 Appeal 28 USC 158<br><input type="checkbox"/> 423 Withdrawal 28 USC 157<br><input type="checkbox"/> 820 Copyrights<br><input type="checkbox"/> 830 Patent<br><input type="checkbox"/> 840 Trademark<br><input type="checkbox"/> 861 HIA (1395ff)<br><input type="checkbox"/> 862 Black Lung (923)<br><input type="checkbox"/> 863 DIWC/DIWW (405(g))<br><input type="checkbox"/> 864 SSID Title XVI<br><input type="checkbox"/> 865 RSI (405(g)) | <input type="checkbox"/> 375 False Claims Act<br><input type="checkbox"/> 400 State Reapportionment<br><input type="checkbox"/> 410 Antitrust<br><input type="checkbox"/> 430 Banks and Banking<br><input type="checkbox"/> 450 Commerce<br><input type="checkbox"/> 460 Deportation<br><input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations<br><input type="checkbox"/> 480 Consumer Credit<br><input type="checkbox"/> 490 Cable/Sat TV<br><input type="checkbox"/> 850 Securities/Commodities/Exchange<br><input type="checkbox"/> 890 Other Statutory Actions<br><input type="checkbox"/> 891 Agricultural Acts<br><input type="checkbox"/> 893 Environmental Matters<br><input type="checkbox"/> 895 Freedom of Information Act<br><input type="checkbox"/> 896 Arbitration<br><input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision<br><input type="checkbox"/> 950 Constitutionality of State Statutes |
| <input type="checkbox"/> 210 Land Condemnation<br><input type="checkbox"/> 220 Foreclosure<br><input type="checkbox"/> 230 Rent Lease & Ejectment<br><input type="checkbox"/> 240 Torts to Land<br><input type="checkbox"/> 245 Tort Product Liability<br><input type="checkbox"/> 290 All Other Real Property  | <input type="checkbox"/> 440 Other Civil Rights<br><input type="checkbox"/> 441 Voting<br><input type="checkbox"/> 442 Employment<br><input type="checkbox"/> 443 Housing/Accommodations<br><input type="checkbox"/> 445 Amer. w/Disabilities Employment<br><input type="checkbox"/> 446 Amer. w/Disabilities Other<br><input type="checkbox"/> 448 Education  | <b>Habeas Corpus:</b><br><input type="checkbox"/> 463 Alien Detainee<br><input type="checkbox"/> 510 Motions to Vacate Sentence<br><input type="checkbox"/> 530 General<br><input type="checkbox"/> 535 Death Penalty<br><b>Other:</b><br><input type="checkbox"/> 540 Mandamus & Other<br><input type="checkbox"/> 550 Civil Rights<br><input type="checkbox"/> 555 Prison Condition<br><input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement  | <input type="checkbox"/> 462 Naturalization Application<br><input type="checkbox"/> 465 Other Immigration Actions  | <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant)<br><input type="checkbox"/> 871 IRS—Third Party 26 USC 7609  |  |

**V. ORIGIN** (Place an "X" in One Box Only)

- ☐ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☒ 6 Multidistrict Litigation

**VI. CAUSE OF ACTION**Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
28 USC 1407Brief description of cause:  
Product Liability Personal Injury**VII. REQUESTED IN COMPLAINT:**☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint:  
JURY DEMAND: ☒ Yes ☐ No**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE Honorable Cynthia M. RufeDOCKET NUMBER 07-md-1871

DATE

10/30/2014

SIGNATURE OF ATTORNEY OF RECORD

s./Barrett Beasley Barrett Beasley

FOR OFFICE USE ONLY

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**CASE MANAGEMENT TRACK DESIGNATION FORM**

|  |  |   |
|--|--|---|
| <p><i>Margaret Thornton</i></p> <p style="text-align: center;">v.</p> <p><i>Gibbs Smith Kline, LLC</i></p> | <p>⋮</p> <p>⋮</p> <p>⋮</p> <p>⋮</p> <p>⋮</p> | <p>CIVIL ACTION</p><br><br><br><br><br><p>NO.</p> |
|--|--|---|

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

**SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:**

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)
- (f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

|                       |                        |                                   |
|-----------------------|------------------------|-----------------------------------|
| <u>10/30/2014</u>     | <u>Barrett Beasley</u> | <u>Plaintiffs</u>                 |
| <b>Date</b>           | <b>Attorney-at-law</b> | <b>Attorney for</b>               |
| <u>(318) 238-1827</u> | <u>(318) 354-1227</u>  | <u>bbeasley@salim-beasley.com</u> |
| <b>Telephone</b>      | <b>FAX Number</b>      | <b>E-Mail Address</b>             |

## UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: Salim-Beasley, LLC 1901 Texas Street, Natchitoches, LA 71457

Address of Defendant: Pepper Hamilton, LLP 3000 Two Logan Square, Philadelphia, PA 19103

Place of Accident, Incident or Transaction: Pineellas, FL  
(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))

Yes ☒ No ☐

Does this case involve multidistrict litigation possibilities?

Yes ☒ No ☐

RELATED CASE, IF ANY:

Case Number: MDL 1871 Judge Cynthia Rufe Date Terminated: \_\_\_\_\_

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?  
Yes ☐ No ☒

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A. Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases  
(Please specify) \_\_\_\_\_

B. Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☒ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases

(Please specify) \_\_\_\_\_

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Barrett Beasley, counsel of record do hereby certify:  
☐ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;  
☐ Relief other than monetary damages is sought.

DATE: 10/30/2014

Barrett Beasley  
Attorney-at-Law

LA 25984

Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 10/30/2014

Barrett Beasley  
Attorney-at-Law

LA 25984

Attorney I.D.#

## UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: Salim-Beasley, LLC 1901 Texas Street, Natchitoches, LA 71457

Address of Defendant: Pepper Hamilton, LLP 3000 Two Logan Square, Philadelphia, PA 19103

Place of Accident, Incident or Transaction: Pinellas, FL  
(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))

Yes ☒ No ☐

Does this case involve multidistrict litigation possibilities?

Yes ☒ No ☐

RELATED CASE, IF ANY:

Case Number: MDL 1871 Judge Cynthia Rufe Date Terminated: \_\_\_\_\_

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?  
Yes ☐ No ☒

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A. Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases  
(Please specify) \_\_\_\_\_

B. Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☒ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases

(Please specify) \_\_\_\_\_

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Barrett Beasley, counsel of record do hereby certify:

☐ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 10/30/2014

Barrett Beasley  
Attorney-at-Law

LA 25984

Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 10/30/2014

Barrett Beasley  
Attorney-at-Law

LA 25984

Attorney I.D.#

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

---

In re: AVANDIA MARKETING, SALES PRACTICES  
AND PRODUCTS LIABILITY LITIGATION

---

)  
) AVANDIA MDL 1871  
)

) HON. CYNTHIA M. RUFE  
)

THIS DOCUMENT RELATES TO:

*Margaret Thornton v. GlaxoSmithKline LLC*

)  
) Case No.  
)

) Trial by Jury Demanded  
)

---

**COMPLAINT**

**COMES NOW** the Plaintiff, Margaret Thornton, by and through the undersigned attorney, and for the Plaintiff's Complaint against GLAXOSMITHKLINE LLC ("GSK", "GlaxoSmithKline" or "Defendant") alleges as follows:

1. This action is brought by the Plaintiff seeking damages for personal injuries and economic damages suffered as a result of a defective and dangerous pharmaceutical product, Avandia (Rosiglitazone maleate) ("Avandia"), which was manufactured, marketed, distributed and/or sold by Defendant.

2. This is a civil action brought on behalf of the Plaintiff regarding damages which occurred as a result of the Plaintiff's ingestion of Avandia. Avandia was manufactured, marketed, distributed and sold to the Plaintiff by GlaxoSmithKline and/or GlaxoSmithKline's representatives.

## **PARTIES**

### **PLAINTIFF**

3. Plaintiff, Margaret Thornton is a citizen and resident of Largo, Florida. Margaret Thornton was sold Avandia in State of Florida. From in or around 2005 to 2008 Margaret Thornton ingested Avandia as prescribed. Margaret Thornton's use of Avandia caused or significantly contributed to negative and detrimental effects to the Plaintiff's heart and cardiovascular system gradually over time and duration, which caused the Plaintiff to suffer coronary artery disease and bypass in or around 2008. As more particularly pleaded below, the Plaintiff maintains that Avandia is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

### **DEFENDANT**

4. GlaxoSmithKline LLC, a Delaware corporation was, and still is a corporation duly existing under and by virtue of the laws of the State of Delaware with its principal place of business in Philadelphia, Pennsylvania. GlaxoSmithKline is duly authorized to conduct business in the State of Illinois.

5. At all times relevant herein, GlaxoSmithKline was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals, including Avandia, and other products for use by the mainstream public, including Plaintiff.

## **JURISDICTION AND VENUE**

6. Pursuant to Rule 7.1 of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, this action was transferred under 28 U.S.C. §1407 to the Eastern District of Pennsylvania for the reasons stated in the Panel's order of October 16, 2007 and, with



the consent of that court, assigned to the Honorable Cynthia M. Rufe for the inclusion in the coordinated or consolidated pretrial proceedings.

7. Pursuant to Judge Cynthia M. Rufe's Order dated May 15, 2014 plaintiffs were severed pursuant Pretrial Order 4. That Order allows the severed plaintiffs to file a complaint in this District, or in another district with proper venue, within thirty (30) days from the date of the severance and, for purposes of the applicable limitation period, will be deemed to have commenced the action on the date of the filing of the multi-plaintiff complaint in which the plaintiff was named.

8. Plaintiffs and Defendants filed a joint stipulation extending the time to file the Plaintiff's Complaint, which was granted by Judge Rufe on August 1, 2014.

### **FACTS**

10. At all times relevant, Defendant GlaxoSmithKline was, and still is a pharmaceutical company involved in researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of pharmaceuticals for distribution, sale and use by the general public, including its antidiabetic agent Rosiglitazone maleate under the trade names of Avandia Tablets, Avandamet Tablets, and Avandaryl Tablets.

11. Rosiglitazone maleate ("Rosiglitazone") is researched, manufactured, sold, merchandised, advertised, promoted, labeled, analyzed, tested, distributed and marketed by the Defendant under the trade names of Avandia Tablets, Avandamet Tablets, and Avandaryl Tablets (hereinafter collectively referred to as "Avandia"), and is a member of the class of drugs known as Thiazolidinediones ("TZDs"). Avandia was first approved for use in treatment of type 2 diabetes mellitus, also known as non-insulin-dependent diabetes mellitus.

12. Most people with diabetes have risk factors such as high blood pressure and cholesterol that provide a pre-existing susceptibility for heart disease and stroke. More than 65 percent of deaths in patient with diabetes are from cardiovascular causes. The effect of any antidiabetic therapy is particularly important because the reason for antidiabetic therapy is to reduce the complications of diabetes, the most serious of which is heart disease.

13. During the past decade, drugs have been introduced for the treatment of type 2 diabetes that, used in monotherapy or in combination therapy, are supposed to better control the disease in patients and reduce health complications associated with diabetes, such as heart attacks, strokes, and other cardiovascular complications.

14. Before and on or about the time when Avandia was prescribed and used by the Plaintiff, type 2 diabetics, the Defendant knew, or should have known, that Avandia was associated with a significant increased risk of heart failure, myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke.

15. The risk of heart failure, also referred to as congestive heart failure, in patients taking Avandia led to labeling revisions as marketing experience and the results of further clinical trials were reviewed by the Food and Drug Administration.

16. On August 14, 2007, the warnings, precautions and contraindications sections of the Avandia label were changed regarding the potential increased risk of heart failure, and the following new black box warning was added to the label:

**WARNING: CONGESTIVE HEART FAILURE**

Thiazolidinediones, including Rosiglitazone, cause or exacerbate congestive heart failure in some patients (see WARNINGS). After initiation of AVANDIA, and after dose increases, observe patient carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed



according to current standards of care. Furthermore, discontinuation or dose reduction of AVANDIA must be considered.

AVANDIA is not recommended in patients with symptomatic heart failure. Initiation of AVANDIA in patients with established NYHA Class III or IV heart failure is contraindicated. (See CONTRAINDICATIONS and WARNINGS.)

17. On November 19, 2007, the warnings, precautions, and indications sections of the Avandia label were changed again regarding the potential risk of myocardial ischemia, and the following language was added to the black box warning:

**WARNING: CONGESTIVE HEART FAILURE AND  
MYOCARDIAL ISCHEMIA**

A meta-analysis of 42 clinical studies (mean duration 6 months; 14,237 total patients), most of which compared AVANDIA to placebo, showed AVANDIA to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. Three other studies (mean duration 41 months; 14,067 patients), comparing AVANDIA to some other approved antidiabetic agents or placebo, have not confirmed or excluded this risk. In their entirety, the available data on the risk of myocardial ischemia are inconclusive.

18. Before the label changes on August 14, 2007 and November 19, 2007, Plaintiff ingested Avandia in the state of Florida.

19. As a direct and proximate cause of ingesting Avandia, the Plaintiff suffered injury.

20. During the entire time Avandia has been on the market in the United States, FDA regulations have required Defendant to revise labeling “to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with the drug; and causal relationship need not have been definitely established.” 21 C.F.R. 201.57(c)(6)(i). This regulation allowed the Defendant to issue such a warning without prior FDA approval.

21. Before and at or about the time of Plaintiff's ingestion of Avandia, the Defendant had the knowledge, the means, and the duty to provide the medical community and the consuming public with more accurate, descriptive information and more adequate warnings regarding the association between Avandia and heart failure, and the association between Avandia and myocardial ischemia and ischemic events such as cardiovascular mortality, and myocardial infarction, through all means necessary, including, but not limited to, labeling, continuing education, symposia, posters, sales calls to doctors, advertisements and promotional materials.

22. At all times relevant, the Defendant failed and refused to warn prescribing medical providers, and the consuming public, including the Plaintiff herein, of the risks associated with Avandia that were known, or should have been known, as alleged herein.

23. At all times relevant, the Defendant engaged in extensive mass media direct-to-consumer promotion, education, and advertising of Avandia for the purpose of increasing sales and stimulating consumer requests for Avandia prescriptions, independent of the advice of medical professionals.

24. At all times relevant, the Defendant was under a duty to exercise reasonable care in the researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of Avandia for distribution, sale and use by the general public, including the Plaintiff herein, to ensure that Avandia's use did not result in avoidable injuries.

25. Plaintiff's injuries as described herein were caused by the negligence of the Defendant, through its agents, servants and/or employees acting within the course and scope of their employment in one or more of the following ways:

- a) Failed to exercise reasonable care in researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing Avandia;
- b) Failed to fully disclose the results of the testing and other information in its possession regarding the association between Avandia and heart failure, and the association between Avandia and myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke;
- c) Failed to adequately warn the medical community and the general public including Plaintiff and the Plaintiff's treating and prescribing medical providers, of the dangers of using Avandia;
- d) At all times pertinent hereto and on or before the period of time that Plaintiff ingested the drug Avandia, the Defendant:
  - 1) continually received reports from clinical trials, physicians, patients, and regulatory authorities of adverse events that occur in patients taking Avandia;
  - 2) had the means and the resources to perform its *pharmaco-vigilance* duties for the entire time Avandia had been on the market in the United States;
  - 3) had a duty to monitor epidemiological and *pharmaco-vigilance* data regarding its drugs and promptly report to the FDA, medical professionals, and the public, including the Plaintiff herein, any safety concerns that arise through epidemiologic study or data;
  - 4) breached its duty with respect to Plaintiff, and the Plaintiff's treating and prescribing medical providers for the reason that Defendant learned or should have learned, through various sources, including but not limited to, clinical trials and other adverse event reports, that there was a substantial risk of heart failure, myocardial ischemia and ischemic events such cardiovascular mortality, myocardial infarction, and stroke associated with the use of Avandia; and,
  - 5) failed to inform doctors, regulatory agencies, and ordinary consumers, including Plaintiff, of this risk.
- e) Failed to exercise reasonable care by over-promoting and promoting Avandia in an unreasonable way, without regard to its potential dangers.

26. As a direct and proximate result of the conduct of the Defendant as set forth above, the Plaintiff became ill and was impaired in the Plaintiff's health, strength, and activity,

sustaining injury to the Plaintiff's body and person, incurred medical expenses, lost wages, suffered disability, suffered pain and will in all respects in the future.

**COUNT I**

**STRICT PRODUCT LIABILITY  
(FAILURE TO WARN)**

27. Plaintiff repeats and re-alleges the allegations set forth in the paragraphs above as if fully set forth herein.

28. The Avandia manufactured and/or supplied by Defendant was unaccompanied by proper warnings regarding all possible adverse side-effects and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. Defendant failed to perform adequate testing in that adequate testing would have shown that Avandia possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made with respect to the use of Avandia. Had the testing been adequately performed, the product would have been allowed to enter the market, if at all, only with warnings that would have clearly and completely identified the risks and dangers of the drug.

29. The Avandia manufactured and/or distributed and/or supplied by Defendant was defective due to inadequate post-marketing warning or instruction because Defendant failed to provide adequate warnings to users or consumers of Avandia and continued to aggressively promote Avandia.

30. As the proximate cause and legal result of the defective condition of Avandia as manufactured and/or supplied and/or distributed by Defendant, and as a direct and legal result of the conduct of Defendant described herein, Plaintiff has been damaged.

WHEREFORE, the Plaintiff demands judgment in the Plaintiff's favor and against GlaxoSmithKline in a sum in excess of \$50,000; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

**COUNT II**

**STRICT PRODUCT LIABILITY  
(DESIGN DEFECT)**

31. Plaintiff repeats and re-alleges the allegations set forth in the paragraphs above as if fully set forth herein.

32. The Avandia manufactured and/or distributed and/or supplied by Defendant was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design and formulation of the drug.

33. Alternatively, the Avandia manufactured and/or distributed and/or supplied by Defendant was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than alternative drugs available for the treatment of type 2 diabetes mellitus.

34. There existed, at all times material hereto, safer alternative medications.

35. Defendant did not perform adequate testing upon Avandia. Adequate testing would have revealed that Avandia causes serious adverse effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made.

36. The Avandia manufactured, designed, marketed, distributed and/or sold by Defendant was unaccompanied by proper and adequate warnings regarding adverse effects

associated with the use of Avandia, and the severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of adverse effects and did not accurately relate the lack of efficacy.

37. Defendant did not warn the FDA of material facts regarding the safety and efficacy of Avandia, which facts Defendant knew or should have known.

38. The Avandia manufactured and/or distributed and/or supplied by Defendant was defective due to inadequate post-marketing warning or instruction because, after the Defendant knew or should have known of the risk of injury from Avandia, they failed to provide adequate warnings to users or consumers of Avandia and continued to promote Avandia.

39. As a result of the defective condition of Avandia, Plaintiff has suffered damage and injury.

WHEREFORE, the Plaintiff demands judgment in the Plaintiff's favor and against GlaxoSmithKline in a sum in excess of \$50,000; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

#### **PRAYER**

WHEREFORE, the Plaintiff demands judgment in the Plaintiff's favor and against GlaxoSmithKline in a sum in excess of the jurisdictional requirement of this Court; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried before a jury.



Respectfully Submitted,



Barrett Beasley  
Salim-Beasley, LLC  
1901 Texas Street  
Natchitoches, LA 71457  
(318) 238-1827  
(318) 354-1227 facsimile

Robert L. Salim  
Salim-Beasley, LLC  
1901 Texas Street  
Natchitoches, LA 71457  
(318) 352-5999  
(318) 352-5998 facsimile

***Attorneys for Plaintiff***